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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,327	05/25/2000	Neil H. Riordan	RIORD.004A	7262

20995 7590 08/30/2002

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 08/30/2002 15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/579,327	Riordan et al
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-21 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Additionally, Applicant's amendment filed April 23, 2002 has been received and entered. Consequently claims 1-21 are pending in the instant application.

All grounds of rejection in the Office Action mailed October 23, 2001 and the Advisory Action mailed February 26, 2002 are withdrawn.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

1. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "removing large cellular components." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what would distinguish a large component from a medium sized component or a small component? Without a clear definition as to the metes and bounds of "removing large cellular components" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was

not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-3, 6, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Pancholi *et al.*

The claims are directed to a method for producing an immune stimulating composition comprising:

treating bacteria containing peptidoglycan with an acid having a pH less than pH 7;

removing large cellular componets from the solution resulting from said treating; and

saving the remaining solution and adjusting the pH to a physiologically acceptable pH.

Pancholi *et al* (U.S. Patent Number 6,190,659) disclose of preparing cell wall extracts of *Streptococcus* suspended in 50mM Tris-HCl buffer pH 6.8 containing 5mM EDTA, 5mM $MgCl_2$ and 30% raffinose. Pancholi *et al* further disclose that the cell wall extracts were then separated by centrifugation. (See column 41).

In view that Pancholi *et al* disclose a method of preparing a cell wall extract which comprises treating bacteria containing a peptidoglycan with an acid having a pH less than 7, and further removing large cellular components (e.g., centrifugation), while saving the remaining

solution, which is at a physiologically acceptable pH, the disclosure of Pancholi *et al* is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai *et al* in view of Pancholi *et al* and Converse *et al*.

The claims are directed to a method for producing an immune stimulating composition comprising:

treating bacteria containing peptidoglycan with an acid having a pH less than pH 7;

removing large cellular componets from the solution resulting from said treating; and

saving the remaining solution and adjusting the pH to a physiologically acceptable pH, wherein said bacteria is *L. fermentum*, and wherein lipids are removed from the remaining solution.

Kawai *et al* (U.S. Patent Number 4,746,512) teach of soluble extracts of *L. fermentum* which have strong inhibitory effects on the gowth of *S. mutans* causing dental caries and *Bacteroides* causing periodontitis, and that these water soluble extracts have shown no toxicity in animal experiments and have no influence on intestinal microflora when orally administered. Kawai *et al* further disclose of preparing these water soluble extracts by heating to 115°C followed by centrifugation. (See columns 2 and 6).

Kawai *et al* do not teach of using an acid with a pH of less than 7 to prepare the cell wall extract, or of removing lipids.

Pancholi *et al* (U.S. Patent Number 6,190,659) teach of preparing cell wall extracts comprising treating Gram positive microorganisms with an acid with a pH of less than 7.

Converse *et al* (Lipoprotein Analysis 1992 IRL Press at Oxford University Press, pp 232-234) teach of a method of lipid extraction. Converse *et al* further teach of a method of removing

lipids using chloroform. Converse *et al* further teach of the deleterious effects of lipid in a composition to be given to an animal.

Given that, 1) Kawai *et al* has taught of methods of preparing soluble extracts of *L. fermentum* which have been shown to inhibit the growth of *S. mutans* causing dental caries and *Bacteroides* causing periodontitis, and that 2) Pancholi *et al* have taught methods of preparing cell wall extracts using an acid with a pH of less than 7, and that Converse *et al* teach of the desirability for removing lipids from compositions to be administered, it would have been prima facie obvious to one of ordinary skill in the art to have incorporated the method of using an acid with a pH of less than 7 to prepare a water soluble extract from *L. fermentum* as taught by Pancholi *et al* and Kawai *et al*, and to further remove lipid from the composition as taught by Converse *et al*. One would have been motivated to produce such a method based on the success of obtaining a cell wall extract for *in vivo* administration using either an acid with a pH of less than 7, as shown by Pancholi *et al* or of obtaining a cell wall extract using hot water as shown by Kawai *et al*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

August 28, 2002